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**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

TEVA BRANDED  
PHARMACEUTICAL PRODUCTS  
R&D, INC., AND NORTON  
(WATERFORD) LTD.,

PLAINTIFFS,

V.

CIPLA LTD.

DEFENDANT

Consolidated Civil Action No.  
2:20-CV-10172-JXN-MAH

Trial: November 16-18, 2022

## CIPLA'S OPENING POST-TRIAL BRIEF REGARDING PATENT INVALIDITY

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## **I. INTRODUCTION**

Plaintiffs did not invent metered-dose inhalers, dose-counters for inhalers, or the drug substance used in Cipla's Product. Plaintiffs were not even the first company to sell Qvar<sup>®</sup>. Rather, motivated by the FDA's 2003 guidance on dose-counters, Plaintiffs designed and patented a specific tape-based dose-counter and inhaler body for use in their metered-dose inhalers ("MDIs"). Plaintiffs now seek to expand their patent claims to cover a drastically different, gear-based dose-counter and inhaler body design utilized in Cipla's Product. To the extent Plaintiffs' patent claims are truly that broad, they are invalid as obvious over the prior art.

Regarding the '808 Patent, Plaintiffs' attempt to turn Cipla's leaf spring into the claimed "regulator" of asserted claim 28, while simultaneously arguing the **exact same leaf spring** in the same dose-counter disclosed in the '406 Publication somehow does not meet the claimed "regulator" or the force limitations strains credulity. Dr. Lewis's testimony regarding the leaf spring is untenable and one of many examples highlighting his lack of credibility.

For an additional and independent reason, claim 28 of the '808 Patent is invalid in view of the '552 Publication, which discloses the same regulator as the '808 Patent. The inventors confirmed this at trial, testifying that the projections or nubs on the split-hub, present in embodiments in both the '808 Patent and the '552 Publication, are the claimed regulator. Plaintiffs and Dr. Lewis would have this

Court believe that somehow Cipla's leaf spring is the claimed regulator, but the projections or nubs on the split-hub of the '552 Publication **are not**, despite being essentially identical to the projections or nubs in '808 Patent. Dr. Lewis's testimony completely ignores that of the inventors, and again illustrates his lack of credibility.

The '289 and '587 Patents ("Common Plane Patents") are invalid in view of the '406 Publication in combination with the '514 Publication. **Plaintiffs'** expert admitted that the '406 Publication discloses a "fantastic" design, however, he argued that the '406 Publication does not disclose ribs in a "common plane" in that fantastic design. There is no good-faith dispute that adding four equally spaced ribs to the inhaler body and dose-counter disclosed in the '406 Publication as shown in the '514 Publication would disclose every limitation of the asserted claims of the Common Plane Patents. There is also no genuine dispute that the use of four equally spaced ribs was "an important feature" of prior-art inhalers used to reduce rocking of the canister. Given the well-known use of four equally spaced ribs, adding such structures to the "fantastic" '406 Publication design would have been obvious.

Faced with unequivocal evidence that their infringement allegations, if accepted, would render the Asserted Claims invalid, Plaintiffs besieged the Court with arguments and insinuations irrelevant to obviousness. First, Plaintiffs touted the fact all but one of the prior art references was before the Patent and Trademark Office ("PTO") during prosecution. But the reference not before the PTO was the most

important in view of Plaintiffs’ broad infringement contentions: **the ’406 Publication, disclosing the same dose-counter and very similar inhaler body design used in Cipla’s Product.** Second, Dr. Lewis argued that a person of ordinary skill in the art (“POSA”) would have found other devices **more** obvious. But, as a matter of law, **all** obvious embodiments are invalid, not merely the “most obvious” embodiment. Third, Plaintiffs argued the prior art references could not be bodily incorporated into each other, while ignoring Federal Circuit precedent rejecting such a requirement. In an attempt to salvage their patents, Plaintiffs relied on the leading and conclusory testimony of Dr. Lewis. But Dr. Lewis’s testimony is contrary to his own prior publications and lacks credibility. If the Court were to find infringement, the Asserted Claims should be held invalid.

## **II. LEGAL STANDARDS**

A claim is obvious if “the differences between the subject matter of the claim sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in the art . . . .” *KSR Int’l Co. v. Teleflex Inc.* 550 U.S. 398, 405 (2007). A claim would have been obvious when each limitation is disclosed in the prior art, and there would have been a reason which would prompt a POSA to combine all elements in the claimed way. *Id.* at 418. “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable

results.” *Id.* at 416. There are four primary factors considered in assessing obviousness: (1) the scope and content of the prior art, (2) differences between the prior art and the claims, (3) the level of ordinary skill in the pertinent art, and (4) secondary considerations of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). The obviousness inquiry is performed from the perspective of a POSA at the time of the alleged invention. *Id.* at 15.

Obviousness requires that a POSA would have been motivated to combine or modify the prior art with a reasonable expectation of success. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007). “[A] patent can be obvious in light of a single prior art reference if it would have been obvious to modify that reference to arrive at the patented invention.” *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1361 (Fed. Cir. 2016). When obviousness is based on two or more references, the proponent must show that a POSA had reason to combine the elements in the manner claimed. *Senju Pharm. Co. v. Lupin Ltd.*, 780 F.3d 1337, 1341 (Fed. Cir. 2015).

“What a reference teaches or suggests must be examined in the context of the knowledge, skill, and reasoning ability of a skilled artisan,” and “is not . . . limited to what a reference specifically ‘talks about’ . . . .” *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1380 (Fed. Cir. 2005). An obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of

ordinary skill in the art would employ.” *KSR*, 550 U.S. at 418. Even if not expressly disclosed in the prior art, “experimental details that one of ordinary skill would have utilized via routine experimentation, armed with the principles disclosed in the prior art,” are insufficient to confer patentability to obvious subject matter. *See Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724, 730 (Fed. Cir. 2017).

A POSA is presumed to have full knowledge of all pertinent prior art. *Airbus S.A.S. v. Firepass Corp.*, 941 F.3d 1374, 1380 (Fed. Cir. 2019). There is no requirement that “a particular combination must be the preferred, or the most desirable, combination described in the prior art in order to provide motivation for the current invention.” *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004). A determination of obviousness does not require an actual physical substitution of elements. *In re Etter*, 756 F.2d 852, 859 (Fed. Cir. 1985) (en banc) (holding physical incorporation argument irrelevant because the test is “not whether the references could be physically combined but whether the claimed inventions are rendered obvious by the teachings of the prior art as a whole.”)

### **III. THE PERSON OF ORDINARY SKILL IN THE ART**

A POSA is “someone with at least a bachelor’s degree in pharma science or a related discipline with at least two to three years of product development experience with the design and manufacture of metered dose inhalers.” Trial Transcript (hereinafter “Tr.”), 547:21-25. “Alternatively, a POSA could have a master’s degree

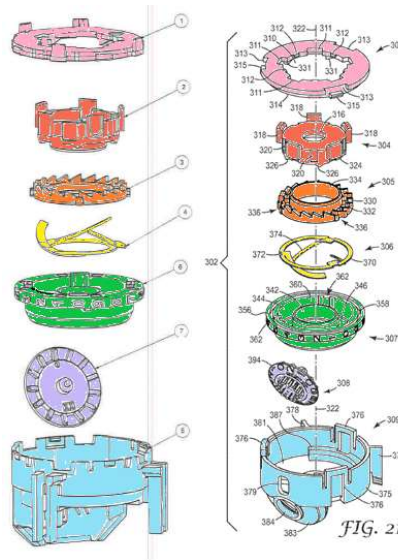
or a Ph.D., again, pharmaceutical science; mechanical, or medical device engineering; or a related discipline with . . . one to two years of product development experience with metered dose inhalers and counter systems.” Tr., 548:1-5. “[A] POSA would also have worked as part of a multi-disciplinary team of scientists in pursuit of developing a pharmaceutical product and drawn upon not only his own skills, but also those -- consulted with others of a team with similar specialized skills.” Tr., 548:6-10; Cipla’s Proposed Findings of Fact and Conclusions of Law Regarding Patent Invalidity (“FOF/COL”), ¶ 26, submitted concurrently herewith. Both experts agreed that any dispute over the definition of the POSA did not impact their opinions. Tr., 548:24-549:1, 674:14-20; FOF/COL, ¶¶ 27-28.

#### **IV. SCOPE AND CONTENT OF THE PRIOR ART**

##### **A. The ’406 Publication (DTX-161)**

WO 2007/124406 (“the ’406 Publication”) is titled “Dose Counter,” lists 3M Innovative Properties Co. (“3M”) as the applicant, and is prior art to the Asserted Patents. DTX-161; D.I. 210, Undisputed Fact 16.h. Given Plaintiffs’ overreaching infringement allegations—and the fact Cipla’s dose-counter relies on the same mechanism of action and components as this prior art (*see, e.g.*, Tr., 757:22-758:1; 758:11-19; 758:23-759:4; 759:22-760:12; 761:13-18 762:11-20)—the ’406 Publication is critical prior art. Yet Plaintiffs failed to submit it to the PTO and the PTO **never considered** it during prosecution of any Asserted Claim. FOF/COL,

¶ 47. The structural similarities between Cipla's dose-counter and the '406 Publication are shown below:



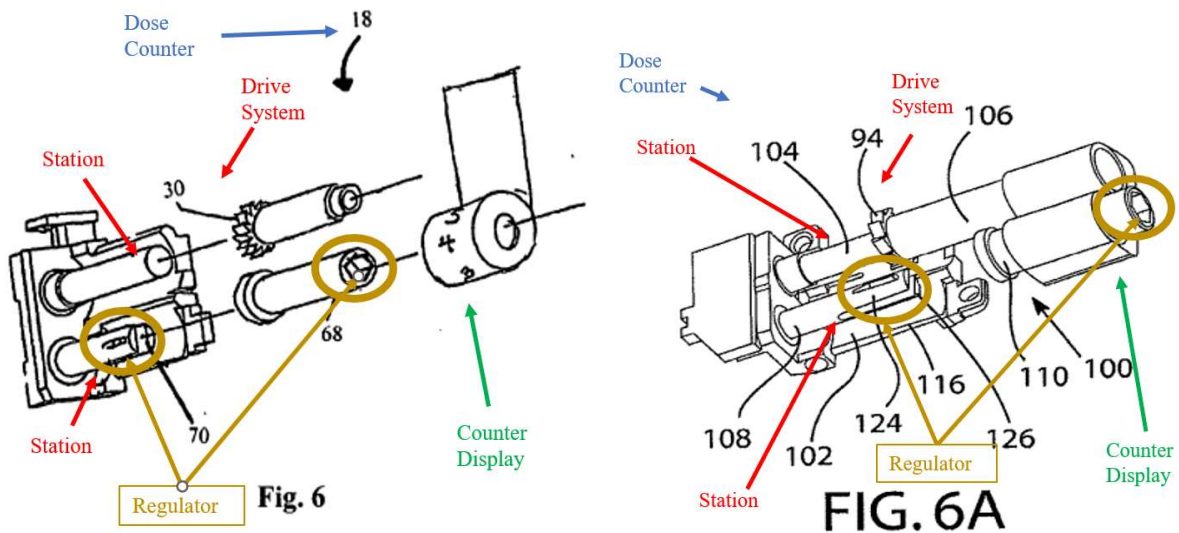
PTX-372 (above left, colored, showing Cipla's dose-counter); DTX-161 at Figure 21 (prior art, colored); FOF/COL, ¶¶ 48, 50.

The '406 Publication describes a gear-based dose-counter design that Plaintiffs' expert characterized as "fantastic." Tr., 748:8-14. Its applicant, 3M, launched the first CFC-free MDI, the first breath-actuated MDI, and originally launched Qvar<sup>®</sup>. *Id.*, 776:1-18. Dr. Lewis agreed 3M was a "big name in inhalers" and described 3M as "very impressive." *Id.*; FOF/COL, ¶¶ 45-46. Indeed, before the alleged invention of the Asserted Claims, Plaintiffs had information regarding 3M's "Integrated Dose-by-Dose Counter," which, like the '406 Publication, contained an integrated counter and contained "7 components" including "1 metal spring" and was covered by "2 filed patents." DTX-109, 3-4; Tr. 108:2-110:13.

The '406 Publication recognizes that “[w]hen a dose counter is integrated into the housing . . . it is desirable to minimize its complexity and ease of installation, as well as to provide an arrangement which is as compact as possible, yet which provides a readily reliable and readable medication dosage count to a user.” DTX-161, [0006]. The reference states that its design meets these needs and provides for a “compact counter,” which is “less influential on product performance, e.g., the airflow of the inhaler.” *Id.*, [0009]. This is achieved in part by a dose-counter that “is designed to minimize interference and obstruction of the medication spray and airflow paths in the actuator housing[.]” *Id.*, [00124]. Moreover, the dose-counter is “designed to be useable with a variety of metering valve designs, and to fit compactly within commercially available actuator housing profiles so that it is not necessary to change the external configuration of those actuator housings to accommodate the inventive dose counter[.]” *Id.*

#### **B. The '552 Publication (DTX-162)**

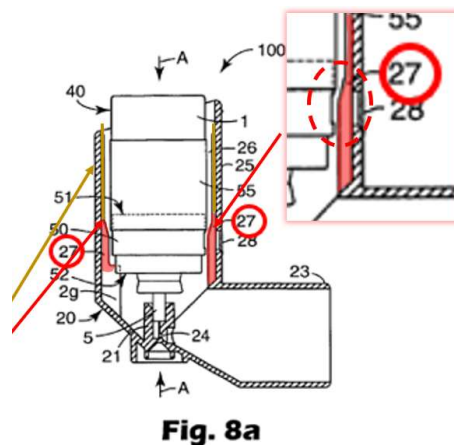
WO 2008/119552 (“the '552 Publication”) is titled “Metered-Dose Inhaler” and is prior art to the Asserted Patents. DTX-162; D.I. 210, Undisputed Fact 16.i. The abstract states it “relates to a metered dose inhaler dose counter,” and the specification describes a tape-based dose-counter design. DTX-162 at Abstract. The structure disclosed in the '552 Publication is similar to the '808 Patent and operates in the same way as the regulator disclosed in the '808 Patent. FOF/COL, ¶¶ 53-54.



Tr., 552:23-555:20; DTX-162, Fig. 6 (annotated); JTX-002, Fig. 6A (annotated).

### C. The '514 Publication (DTX-165) and Other References Teaching the Use of Ribs

WO 2003/101514 (“the '514 Publication”) is titled “Dose Indicators and Dispensing Canister-Indicator Assemblies” and is prior art to the Asserted Patents. DTX-165; D.I. 210, Undisputed Fact 16.j. The '514 Publication discloses four support ribs (27), which extend inwardly from the main surface of the inner wall. DTX-165, 16:17-19; 25:19-22 and Figs. 11a, 12a. These ribs are in red in Fig. 8a:



DTX-165, Fig. 8a (annotated); *id.*, 14:17-19 (“One or more ribs (27) may be positioned within the chamber of the cylindrical portion to aid in locating and supporting the containers in the correct position.”); FOF/COL, ¶¶ 57-58.

Numerous other references illustrate the ubiquitous use of ribs in inhaler bodies. For example, U.S. Patent No. 4,817,822 states “[s]pacer ribs . . . may be provided inside the housing to hold the external surface of the contained spaced from the internal surface of the housing.” DTX-137, 5:37-40. Such ribs are also commonplace in other prior art. *E.g.*, DTX-172, Fig. 1C; DTX-174, Fig. 6; DTX-153, Fig. 7; FOF/COL, ¶¶ 59-60.

Plaintiffs’ own expert wrote about the “conventional” and “important” use of such ribs. Dr. Lewis wrote in a prior art 2007 peer-reviewed journal article that around 1965 “four equally spaced ribs” were added to inhalers and “provided an annular passageway to draw air using the mouthpiece” and stated this “updated design remains an important feature of present actuators.” Tr., 773:7-25; PTX-099, 236. In his own patent filings, Dr. Lewis referred to the use of ribs as “conventional.” DTX-223, [0026]. Dr. Lewis’s patent publication even shows four equally spaced ribs, similar to the ’514 Publication. *Id.*, [0026], Fig. 3; FOF/COL, ¶¶ 61-63. Consistent with the prior art, the named inventors testified that ribs were known. Trial Tr. at 80:18-24; FOF/COL, ¶¶ 64-65.

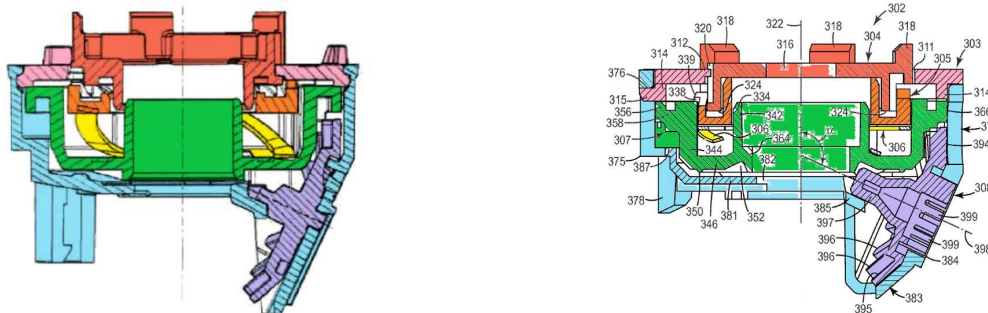
## **V. THE ASSERTED CLAIM OF THE '808 PATENT IS INVALID**

If Cipla's Product infringes, then claim 28 of the '808 Patent would have been obvious over the '406 Publication or the '552 Publication. FOF/COL, ¶¶ 66-122.

### **A. If Cipla Infringes, Claim 28 of the '808 Patent Would Have Been Obvious Over the '406 Publication**

#### **1. Cipla's Dose-Counter and the '406 Publication Dose-Counter Share the Same Mechanism of Action and Structural Features**

Mr. Anderson provided a detailed explanation of how the dose-counter of Cipla's Product matches the disclosure of the '406 Publication. Mr. Anderson explained how Cipla's Product has "every single component that we discussed today, [in] the '406 [Publication]." Tr., 560:1-4, 560:20-25. In support of his conclusion, Mr. Anderson provided the below comparison between a schematic drawing of the dose-counter in Cipla's Product and the dose-counter disclosed in Fig. 26 of the '406 Publication:



PTX-372 (colored); DTX-161, Fig. 26 (colored).

After reviewing the above comparison between the dose-counter of Cipla's Product and the dose-counter disclosed in the '406 Publication, Mr. Anderson

concluded “when you have a look at the number [of components] and the way they are laid out, they are the same.” Tr., 563:12-15. In short, Cipla’s dose-counter is practicing the ’406 Publication. Claim 28 of the ’808 Patent cannot be treated differently in an infringement analysis from how it would be treated under an invalidity analysis. *See Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001) (“the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses”). Thus, if Cipla’s Product infringes claim 28 of the ’808 Patent, the ’406 Publication renders claim 28 obvious because it discloses a dose-counter containing the same operational components as the dose-counter in Cipla’s Product. FOF/COL, ¶¶ 72-77

Despite the facially apparent similarities between the ’406 Publication and Cipla’s Product, Dr. Lewis testified that in his opinion “what is described in the ’406 is entirely different to the defendant’s products.” Tr., 745:20-746:1. Dr. Lewis bizarrely attempted to justify the fact the ’406 Publication was not before the examiner during prosecution of the Asserted Claims by saying it is “completely different to the defendant’s product,” (Tr., 753:1-8) and then later contradicted himself (Tr., 758:1 and 762:17). Dr. Lewis’s belief that the ’406 Publication is nothing like Cipla’s Product, but Cipla’s Product is similar to the tape-based systems disclosed in the Asserted Patents is simply not credible. FOF/COL, ¶¶ 207-211.

## **2. If Cipla's Leaf Spring is a "Regulator," So is the Leaf Spring in the '406 Publication**

Claim 28, through its dependency from claim 1 of the '808 Patent, recites a regulator "arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements." Plaintiffs contend that the leaf spring in Cipla's dose-counter is the claimed "regulator" that "regulate[s] motion of the counter display at the first station to incremental movements." Tr., 290:19-291:10. Yet, Dr. Lewis ignores that the dose-counter disclosed in the '406 Publication has the same leaf spring found in Cipla's Product. *Compare* PTX-372 (Cipla's dose-counter); DTX-161, Fig. 26 and [00142] and [0098] (disclosing the same leaf spring as Cipla's and explaining that the leaf spring can be flipped). Dr. Lewis conceded that "there are similarities" between the dose-counter disclosed in the '406 Publication and Cipla's Product, and that the dose-counter in the '406 Publication "looks the same" as the dose-counter used in Cipla's Product. Tr., 758:1 and 762:17. Thus, if Cipla's Product is found to meet each limitation of claim 1 of the '808 Patent, the '406 Publication similarly discloses each limitation of claim 1. FOF/COL, ¶¶ 75-77.

## **3. The Force Limitation of Claim 28 Does Not Render Claim 28 Non-Obvious.**

With regard to claim 28 of the '808 Patent, Plaintiffs contend that the leaf spring in Cipla's dose-counter provides a resistance force of greater than 0.3 N "against movement of the counter display." Tr., 297:2-24. Operationally, there is no

distinction between the leaf spring in the '406 Publication and Cipla's dose-counter. *Compare* PTX-372; DTX-161, Fig. 26 and [00142] and [0098] (disclosing the same leaf spring as Cipla's and explaining that the leaf spring can be flipped). If the leaf spring in Cipla's Product provides a resistance force "against movement of the counter display," so must the leaf spring in the '406 Publication. Thus, the dose-counter in the '406 Publication must also meet this limitation, as the two dose-counters are essentially the same. *Compare* PTX-372 (Cipla's Product), *with* DTX-161, Fig. 26 ('406 Publication); FOF/COL, ¶¶ 78-80.

The "greater than 0.3 N" resistance force does not render claim 28 non-obvious. Mr. Anderson explained that the claimed force values "are experimental" and based on routine testing. Tr., 557:12-22 (discussing this same claimed force limitation in the context of the '552 Publication prior art analysis). Mr. Anderson further testified "as a matter of routine optimization for any POSA, they would find the appropriate force against movement of the counter display . . . ." *Id.* Likewise, Dr. Lewis conceded a POSA would have been able to calculate the force on the leaf spring in 2009, at the time of the alleged invention, just as he was allegedly able to for his infringement calculations. Tr., 757:10-13; FOF/COL, ¶¶ 81-83, 106-113. The Federal Circuit has held that values easily obtainable via routine optimization, which is the case here, are insufficient to confer patentability on claimed subject matter. *See Merck*, 874 F.3d at 730 ("Experimental details that one of ordinary skill would

have utilized via routine experimentation, armed with the principles disclosed in the prior art,” insufficient to confer patentability to obvious subject matter.).

Moreover, Plaintiffs have failed to show the “greater than 0.3 N” resistance force yields any type of unexpected result sufficient to overcome the strong case of obviousness. The claimed force covers an extremely broad range of any force **greater than** 0.3 N, a minimal force Dr. Lewis characterized as “a very small number.” Tr., 320:12-16. Dr. Lewis testified the purpose of the claimed regulator was to prevent counting errors caused by “nudges” to the inhaler and “prevent unwanted motion of the counter display if the counter is dropped . . . .” *See, e.g., id.*, 182:22-183: 24. Yet, the force caused by dropping an inhaler based on the weight of the inhaler alone approaches 0.3 N. *Id.*, 734:10-18 (Dr. Lewis testifying drop force depends on the mass of the inhaler and the typical inhaler weighs 24 grams, leading to a force of 0.24 N (i.e., “24 grams divided by a thousand times ten roughly”)); FOF/COL, ¶¶ 81-83, 106-113.

Inhalers are also subject to other large forces during routine use. Dr. Lewis testified actuating a device to deliver drug requires a force of 50 N. Tr., 403:7-11. This force is 166 times greater than the minimal 0.3 N force recited in claim 28. Yet the only reason Dr. Lewis testified for a desire to use “small forces” is “you are not going to want to add to much compression to the energy that the patient is going to need to push.” Tr., 728:5-13. Such testimony lacks credibility. FOF/COL, ¶¶ 207-

211. If a POSA expected the patient to exert a force of 50 N to fire the inhaler, the assertion that adding an additional 0.3 N of force due to a regulator would be undesirable is nonsensical.

The calculation of 0.3 N force would have been based on routine experimentation of the desired force for the alleged “regulator.” Plaintiffs have not shown that a POSA would have been incapable of calculating this force or that the force yields any unexpected result. If Cipla’s leaf spring is found to be the claimed “regulator,” found to “regulate motion of the counter display at the first station to incremental movements,” and found to meet the force requirement of claim 28 such that Cipla’s Product is found to infringe claim 28 of the ’808 Patent, claim 28 must be obvious in view of the ’406 Publication, because it merely claims an “optimized” leaf spring covering all meaningful forces.

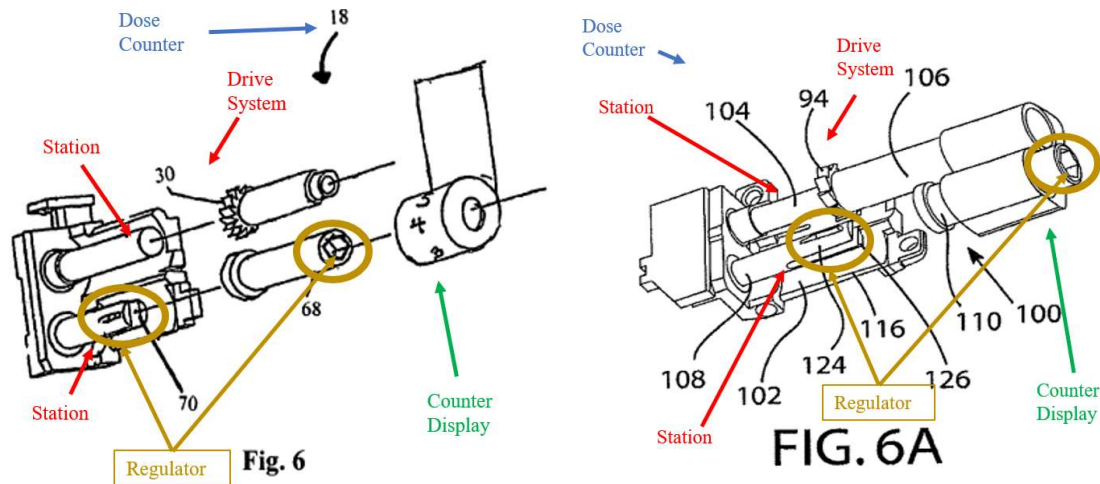
Thus, if Cipla’s Product is found to meet each limitation of claim 28 of the ’808 Patent, claim 28 would have been obvious over the ’406 Publication. FOF/COL, ¶¶ 228-234.

#### **B. Claim 28 Would Have Been Obvious Over the ’552 Publication**

Claim 28 of the ’808 Patent would have also been obvious over the ’552 Publication. The ’552 Publication discloses a tape-based dose-counter just like that described in the ’808 Patent. The claims as construed in this case, however, expand the scope of the ’808 Patent to include nothing more than an obvious variation of the ’552 Publication. Thus, claim 28 of the ’808 Patent is invalid. FOF/COL, ¶¶ 85-122.

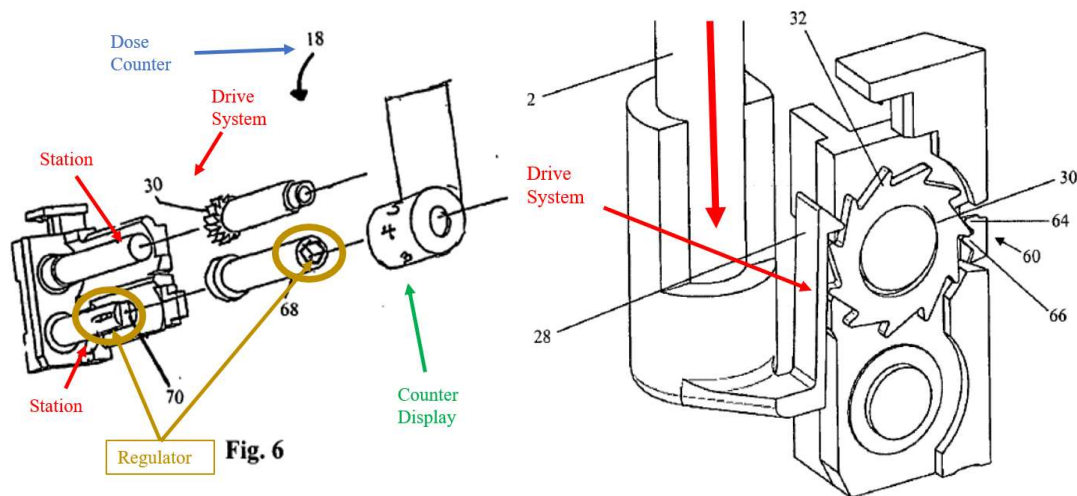
**1. The Limitations Recited in Claim 1 of the '808 Patent are Met by the '552 Publication**

There is no legitimate dispute that the '552 Publication expressly discloses the subject matter recited in claim 1 of the '808 Patent. Indeed, Figure 6 of the '552 Publication is virtually indistinguishable from Figure 6A of the '808 Patent.



DTX-162 ('552 Publication), Fig. 6 (annotated) (left); JTX-002 ('808 Patent), Fig. 6A (annotated) (right); FOF/COL, ¶ 85.

The '552 Publication discloses “a dose counter for an inhaler” as recited in claim 1. Tr., 553:9; *see also* DTX-162, 4:20-31, 8:7-8, 9:9-18, Fig. 6. Figures 5 and 6 of the '552 Publication (below) show its dose-counter:



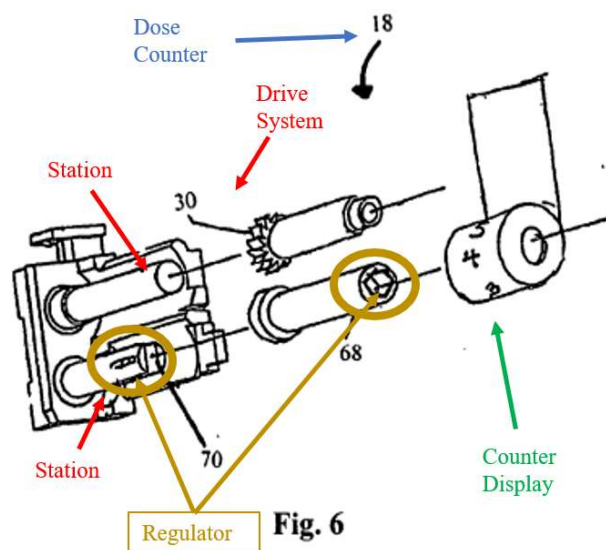
DTX-162, Figs. 6 and 5 (annotated); FOF/COL, ¶¶ 86-88.

The '552 Publication discloses a “dose counter having a counter display arranged to indicate dosage information.” FOF/COL, ¶¶ 89-91. Mr. Anderson testified this “would be the tape shown in green” in annotated Fig. 6 of the '552 Publication. Tr., 553:9-11; DTX-162, Fig. 6, 4:20-31, 8:7-8, 9:9-18.

The '552 Publication discloses “a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input.” FOF/COL, ¶¶ 92-96. In Figures 6 and 5, “[a] drive system arranged to move the counter display incrementally the first direction from the first station which would be the bottom one, 70, up to another station, a second station.” Tr., 553:11-14. Figure 5 provides a detailed illustration of the drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input. *See* DTX-162, Fig. 5.

It is undisputed that the '552 Publication discloses the above limitations. *See* Tr., 763:18-20. Instead, Plaintiffs challenge whether the '552 Publication discloses the regulator recited in claim 1 and as construed by the parties. *See id.* The parties agreed “regulator” means “a structure of the dose counter that modulates motion of the dose counter display.” D.I. 102, 4. In view of that construction, there is no legitimate dispute that the '552 Publication discloses the required “wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.” FOF/COL, ¶¶ 97-105.

Mr. Anderson testified that in Figure 6 of the '552 Publication, reproduced below, “you can actually see the regulator circled -- the bobbin 68 is actually placed over the shaft 70. And you can see on shaft 70 there is a small detail . . . But you can definitely see there is a regulator.” Tr., 553:18-23.

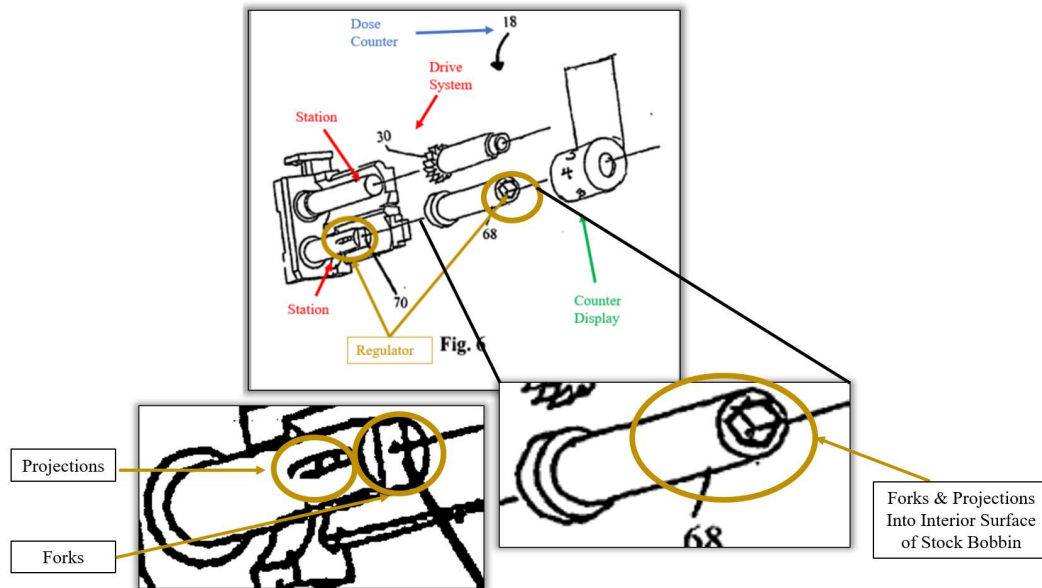


DTX-162, Fig. 6 (annotated). Although the '552 Publication does not use the word “regulator,” the disclosure is fully consistent with the '808 Patent's disclosed regulator structure. FOF/COL, ¶¶ 97-99. The '552 Publication states “the stock bobbin 68 . . . is held taut by the action of the split hub 70.” DTX-162, 9:9-11. After the “next integer” is revealed, “[t]he counter tape 44 is held taut by the action of the split hub 70 on which is mounted the stock bobbin 68.” *Id.*, 10:6-8. Accordingly, the split hub provides a force in connection with the stock bobbin that regulates the motion of the counter display counter tape to incremental movements. *See* Tr., 550:10-18; FOF/COL, ¶¶ 103-105.

The regulator disclosed in the '552 Publication is consistent with the regulator in the '808 Patent. Tr., 554:5-17. Mr. Anderson provided further analysis of the shaft and projections comprising the regulator using an image, reproduced below, stating:

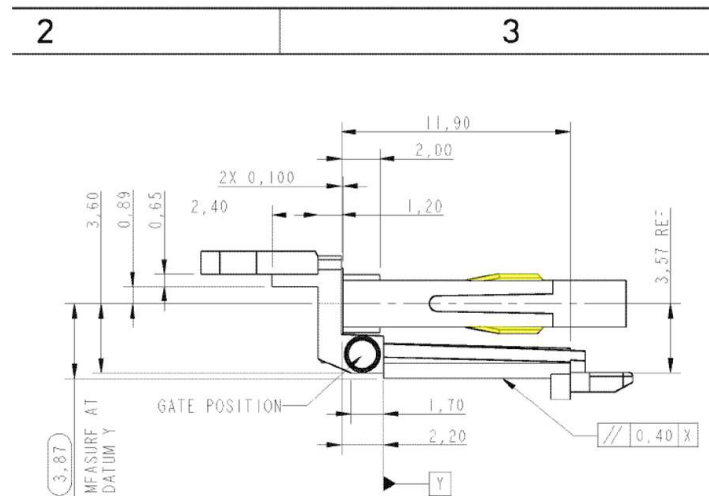
[Y]ou can see here there is a blown-up image of the shaft, the station projections. And you can see that obviously that component there is . . . a forked design. And the forks actually have the shaft slid over it. So, again, a POSA would understand that the '552 publication does disclose a regulator because it discloses the projections and a surface for the projections to actually physically engage with when it will modulate the motion of the counter display to incremental movements.

Tr., 555:10-18.

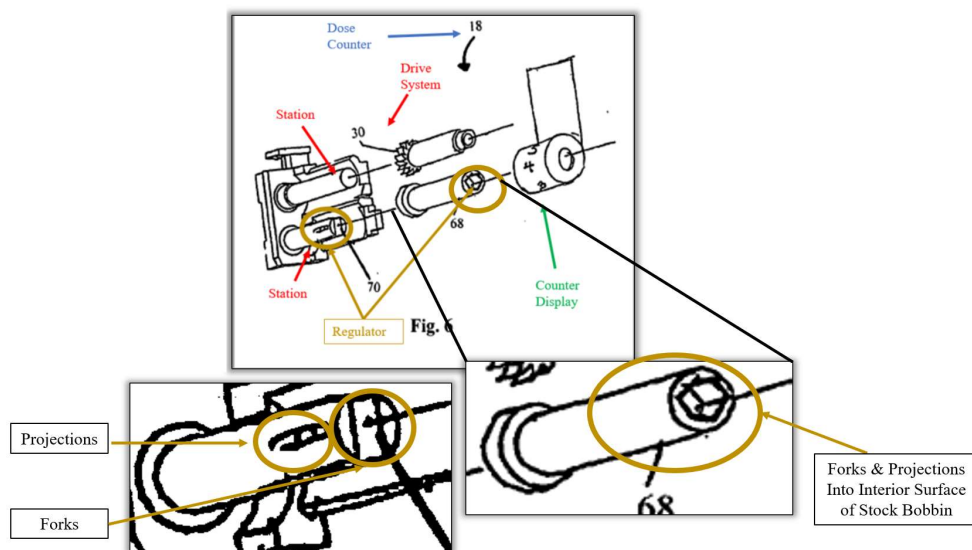


DTX-162, Fig. 6 (annotated). The '552 Publication thus discloses the claimed regulator.

The testimony of Plaintiffs' inventor confirms that Mr. Anderson's testimony is accurate. FOF/COL, ¶¶ 100-102. PTX-231 shows engineering drawings for the actuator body of the inhaler that Teva designed. Tr., 84:11-16. Mr. Walsh explained that PTX-231 showed the purported "regulator" of this '808 Patent. Tr., 84:11-86:18. On direct, Mr. Walsh was asked about a "component that is under the number 3" in PTX-231 (design drawings) on the "page ending in Bates number 027." *Id.*, 84:17-21. That component, which Mr. Walsh described as "one of the most critical components within the counter," *id.*, 84:22-85:5, is shown below:



PTX-231, TEVAQVAR-00462027 (colored). When asked about how they “solve[d] the problem with the counter display moving too much,” Mr. Walsh pointed to this figure as disclosing the “regulator.” Tr., 86:9-18. Specifically, Mr. Walsh pointed to the two features on the “top and bottom of [the] cylindrical pin,” *see id.*, which are highlighted above. PTX-231, TEVAQVAR-00462027 (colored). These two “cylindrical pin[s]” are consistent with the split hub projections in Fig. 6 of the ’552 Publication:



DTX-162, Fig. 6 (annotated); Tr., 554:8-17. Mr. Walsh confirmed Fig. 6F of the '808 Patent also appears to show a regulator. Tr., 106:2-16. Thus, the '808 Patent claim 1 limitations, including the “regulator,” are disclosed by the '552 Publication.

## **2. The Force Limitation Does Not Render Claim 28 Non-Obvious.**

As previously discussed, determining the “greater than 0.3 N force” limitation recited in claim 28 involved mere routine experimentation and optimization. *Supra* Section V.A.3; FOF/COL, ¶¶ 106-113. Inhalers are commonly subjected to forces greater than 0.3 N. Indeed, the '552 Publication indicates that a force of 15 to 30 N is required to activate that device. DTX-162, 1:26-29. Accordingly, a regulator equipped to provide greater than 0.3 N of resistance force would have been obvious.

As Mr. Anderson explained:

[In t]he '808 patent, the force values that are claimed are experimental. And they are based obviously on testing. And as a matter of routine optimization for any POSA, they would find the appropriate force against movement of the counter display to make sure that unwinding of that tape didn't happen while allowing it to drive incrementally to move the counter display. So it's a fine balance between not going backwards, but allowing it to go forwards.

Tr., 557:14-22. A POSA would have used routine experimentation to arrive at the force values necessary to achieve this goal, as explained by Mr. Anderson. Such “[e]xperimental details that one of ordinary skill would have utilized via routine experimentation, armed with the principles disclosed in the prior art,” are insufficient to confer patentability to obvious subject matter. *See Merck*, 874 F.3d at

730. Thus, claim 28 of the '808 Patent would have been obvious. FOF/COL, ¶¶ 106-113.

Dr. Lewis testified Teva's products practice claim 28 of the '808 Patent. Tr., 728:15-25. Dr. Lewis, however, never did any testing of the purported "regulator" in Teva's products, and Dr. Lewis never cited to any testing indicating that there was a force over 0.3 N. Dr. Lewis even testified that he believed it would be very difficult to design such a test. Tr., 767:8-15, 768:4-769:5. If the 0.3 N force was not the product of routine experimentation and optimization, Dr. Lewis could not have reached his conclusion without testing, especially considering there are no documents in the record indicating a resistance force of over 0.3 N is present as claimed. Moreover, a conclusion that a POSA would have been incapable of testing the force, coupled with the fact the patent does not disclose how to test for the force, would mean claim 28 is invalid under 35 U.S.C. § 112. Plaintiffs cannot have it both ways. Claim 28 would have been obvious because it is nothing more than the product of routine experimentation and optimization of the prior art. FOF/COL, ¶¶ 235-241.

**C. The PTAB's Consideration of the '950 Publication Does Not Preclude a Finding of Invalidity**

Plaintiffs contend a finding that the disclosure of the '552 Publication renders claim 28 of the '808 Patent obvious is at odds with the Patent Trial and Appeal Board's ("PTAB") decision regarding patentability of the '808 Patent claims over

U.S. Patent Publication No. 2002/0078950 (“the ’950 Publication”) during prosecution. The Court should reject Plaintiffs’ arguments. FOF/COL, ¶¶ 114-122.

# 1. The Disclosures of the ’552 Publication and ’950 Publication Are Different

The disclosures of the ’950 and ’552 Publications are not the same. Figure 6 of the ’552 Publication and Figure 15 of the ’950 Publication are similar:

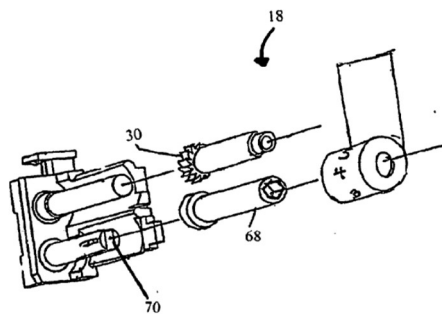


Fig. 6

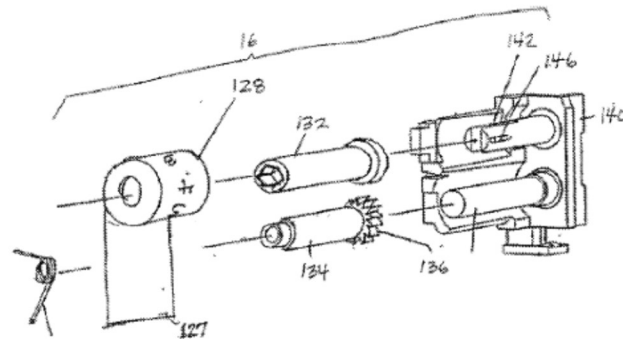


FIG. 15

DTX-162, 24 (left); JTX-006, TEVAQVAR-00027225 (right). But the descriptions of these embodiments within the respective specifications are different.

## Disclosure of ’552 Publication

Fig 6 shows an exploded view of the dose counter 18 showing in addition to the previously described components the stock bobbin 68 which is held taut by the action of the split hub 70. The split hub 70 avoids the need for a clutch spring as set out in WO 98/28033. . . . The display is preferably an elongate counter tape 44 on which the dose count is printed or written, and more preferably the counter tape 44 is located on an indexing spool and the dose counter further comprises a stock bobbin to receive the counter tape as the indexing spool is advanced in **a stepwise fashion**. DTX-162, 9:9-17 (emphasis added).

The spindle of the rotary gear moves the counter tape 44 **revealing the next integer**. The counter tape 44 is held taut by the action of the split hub 70 on which is mounted the stock bobbin 68. *Id.*, 10:6-8 (emphasis added).

<b>Disclosure of the '950 Publication</b>
<p>The bobbin shaft 142 is preferably forked and includes radially nubs 146 for creating a resilient resistance to rotation of the bobbin 132 on the shaft 142. JTX-006, TEVAQVAR-00027255.</p>

As reflected above, the '552 Publication discloses that “split hub 70” is used in a manner to advance the spool in a “stepwise fashion,” “revealing the next integer.” DTX-162, 9:9-17; 10:6-8. The '950 Publication lacks such disclosure. Therefore, unlike the '950 Publication, the '552 Publication does teach a regulator that, as recited in claim 1, “regulates motion of the counter display at the first station to incremental movements.” FOF/COL, ¶¶ 115-117.

During prosecution of the '808 Patent, the PTAB reversed the Examiner's rejection of the claims over the '950 Publication because:

The evidence of record does not adequately support the Examiner's determination that [the '950 Publication's] device is capable of such regulated motion. In particular, [the '950 Publication] is ambiguous whether or not bobbin 132 necessarily has complementary features to match the nubs of shaft 142.

JTX-006, TEVAQVAR-00027225. The '552 Publication does not suffer from this deficiency because it explicitly refers to incremental movement—i.e., movement in a “stepwise fashion.” Although the '552 Publication does not refer to “complementary features to match the nubs,” such features are not required by claim 1 of the '808 Patent. Indeed, as discussed below, such features are found neither on

Cipla's Product nor the "regulator" in Plaintiffs' products, and such complimentary features were not identified by the inventors as part of the claimed "regulator."

## **2. The PTAB Did Not Have Evidence of Plaintiffs' Expansive Interpretation of a "Regulator"**

The PTAB also made its decision without the benefit of seeing how Plaintiffs' have attempted to expand its claim scope to encompass Cipla's Product. FOF/COL, ¶¶ 118-119. Plaintiffs have attempted to expand the reach of "regulator" to include Cipla's leaf spring. But like the '552 Publication, Cipla's leaf spring does not engage with any complimentary feature on another component. Tr., 463:18-464:12 (the leaf spring "just sits there. It's not attached to a frame or anything. It sits inside the unit's counter. It is free to move. It is not constrained. And you wouldn't want it to be ...."). Instead, Plaintiffs allege the leaf spring acts as a "regulator" by applying a force via friction to the counter display. Dr. Lewis equated this to a child stopping a "roundabout" with their foot:

So if I'm on a child's roundabout and I put my - - if I'm - - I put my foot over the edge of this roundabout and then I push my foot down, yes, I'm pushing down on the ground and I am pushing down, but the roundabout will stop. Without my foot pushing down and without any friction, the roundabout will continue.

Tr., 315:2-24. Yet, during prosecution, Plaintiffs differentiated the '950 Publication as not teaching the claimed "regulator," despite the fact it also used frictional forces to resist rotation, using a similar analogy of a brake applied to a bicycle wheel:

The type of "resilient resistance" described by [the '950 Publication] is commonly applied in numerous contexts; for example, common brake

pads on a bicycle wheel provide resilient resistance against a smooth wheel rim, thereby slowing the rotation of the wheel. There is absolutely no requirement for corresponding concavities to achieve the type of resilient resistance described by [the '950 Publication].

JTX-006 at TEVAQVAR-00027183. There is no meaningful difference between a child using his foot to stop rotation on a roundabout and a rider using a break to slow a bicycle wheel. This double speak highlights how Plaintiffs are improperly expanding the scope of the claims for infringement, but narrowing the scope for invalidity. *See Amazon.com*, 239 F.3d at 1351. If the PTAB knew Plaintiffs' position that a structure that merely provided frictional force was sufficient to act as the claimed "regulator," the Examiner's rejection in view of the '950 Publication would have been proper and maintained, and the '808 Patent would not have issued.

### **3. The PTAB Did Not Have the Inventor Testimony from Trial**

Finally, the PTAB made its decision without the benefit of trial testimony regarding the "regulator." FOF/COL, ¶¶ 120-122. Both inventors testified the "regulator" was the projections and **not** the projections in combination with other structure. Tr., 636:21-24 ("We wanted to increase or to reduce the movement, the free movement of the bobbin on the shaft. And we developed these two protrusions to interfere slightly with the internal surface of the bobbin thereby not allowing it to float freely."); 86:3-8 (a regulator is "the two feature shown on the diagram . . . so they are seen top and bottom of that cylindrical pin."); 106:2-5. Indeed, Mr. Walsh confirmed the QVAR and ProAir MDI products as sold never contained any

additional mating structure. *See, e.g.*, Tr., 106:24-108:1. Dr. Lewis’s conclusory testimony that Plaintiffs’ products practice the asserted claims (Tr., 728:19-25) is a tacit admission that an additional “mating” structure is not needed to meet the “regulator” limitation. If the PTAB had this information, it would have had an express basis to maintain the Examiner’s rejection.

Simply put, Plaintiffs’ decision to expand the scope of claim 28 of the ’808 Patent in an attempt to encompass Cipla’s Product renders claim 28 invalid. Thus, the Court should reject Plaintiffs’ argument that the PTAB’s consideration of the ’950 Publication, a reference never asserted at trial, prevents an invalidity finding.

#### **VI. THE ASSERTED CLAIMS OF THE ’289 PATENT ARE INVALID**

Because Plaintiffs are accusing as infringing a dose-counter design using the same components and the same mechanism of action as the ’406 Publication, it is unsurprising that Plaintiffs do not contest that most of the asserted ’289 Patent claim limitations are disclosed in the ’406 Publication. The only asserted ’289 Patent claim limitation not expressly disclosed in the ’406 Publication is the “inner wall canister formation” that is in a “common plane.” But such “inner wall canister formations” were ubiquitous in the art and expressly disclosed in the ’514 Publication. For example, the ’514 Publication discloses four equally spaced ribs, which meet the inner wall canister formation limitation—a rib is located on the back, front, and both sides of the canister. It would have been obvious to add such structures—which were

well-known in the art—to the “fantastic” design of the ’406 Publication. Moreover, by adding them in the location disclosed in the ’514 Publication, the common plane limitation would have been met.

**A. Claim 1 of the ’289 Patent Would Have Been Obvious Over the ’406 Publication in Combination with the ’514 Publication**

**1. Undisputed Limitations Taught in the ’406 Publication**

It is undisputed that the ’406 Publication discloses the majority of the elements in claim 1 of the ’289 Patent. The ’406 Publication discloses an inhaler for metered dose inhalation. Tr., 567:1-5; DTX-161 at Fig. 27, [0067], and [00149]; FOF/COL, ¶¶ 136-137. The ’406 Publication also discloses a main body having a canister housing. Tr., 567:6-10; DTX-161 at Fig. 27, [00149]; FOF/COL, ¶¶ 138-139.

The ’406 Publication discloses a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister. Tr., 567:11-568:12; DTX-161 at Fig. 27, [00104], [00106]; FOF/COL, ¶¶ 140-141.

The ’406 Publication discloses a dose-counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister. Tr., 568:18-23; DTX-161 at Fig. 27, [00137] (disclosing the dose-counter is comprised of an indexer 304 with castellations 318 extending past lid 303 into the canister housing); FOF/COL, ¶¶ 142-145. When the inhaler is actuated, downward movement of the container causes the container to

engage with the castellations, moving the indexer downward. *Id.* at Fig. 27 (castellations 318, valve ferrule 110), [00150], [00106]. The '406 Publication discloses the canister housing has an inner wall. Tr. 569:15-16; DTX-161 at Fig. 27.

## **2. Disputed Limitations Taught by the Combination of the '406 and '514 Publications**

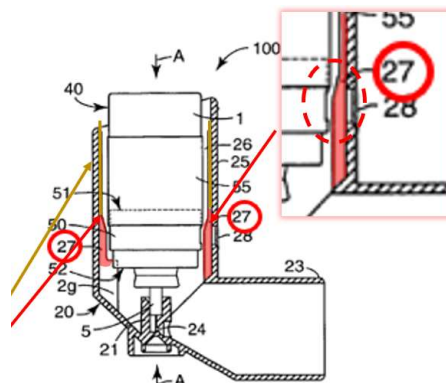
The '406 Publication does not expressly disclose an “inner wall canister support formation” in a “common plane,” which requires “the inner wall canister support formation, the actuation member, and the central outlet” to lie in a common plane coincident with the longitudinal axis X (the “common plane limitation”). But the '514 Publication discloses four inner wall canister formations equally spaced on the front, back, and sides of an inhaler body. DTX-165 at Figs. 2 and 8. If these formations were added to the front, back, and sides of the '406 Publication's inhaler body, as shown in at least Fig 2A of the '514 Publication, then the common plane limitation would have been met. *Id.* at Fig. 2a; FOF/COL, ¶¶ 146-168. The routine addition of known inner wall canister support formations to the '406 Publication is not innovative—it is born of common sense and is obvious. FOF/COL, ¶¶ 146-168.

### **i. *The '514 Publication Discloses Inner Wall Canister Formations***

The '514 Publication discloses “inner wall canister formations,” “extending inwardly from a main surface of the inner wall was commonplace in the prior art before 2010 and they were known as ribs . . . .” Tr., 569:24-570:4. Mr. Anderson explained how the '514 Publication discloses four equally spaced ribs, which act as

inner wall canister support formations, extending inwardly from a main surface of the inner wall. Tr., 573:19-25; FOF/COL, ¶¶ 147-150.

The ribs described by Mr. Anderson at trial are clearly disclosed in the '514 Publication, which discloses support ribs (27) extending inwardly from the main surface of the inner wall. DTX-165 at 25:19-22 and Figs. 11a, 12a. Specifically, the '514 Publication discloses first inner wall canister support formations extending inwardly from the inner wall, shown in Fig. 8a, below in red.

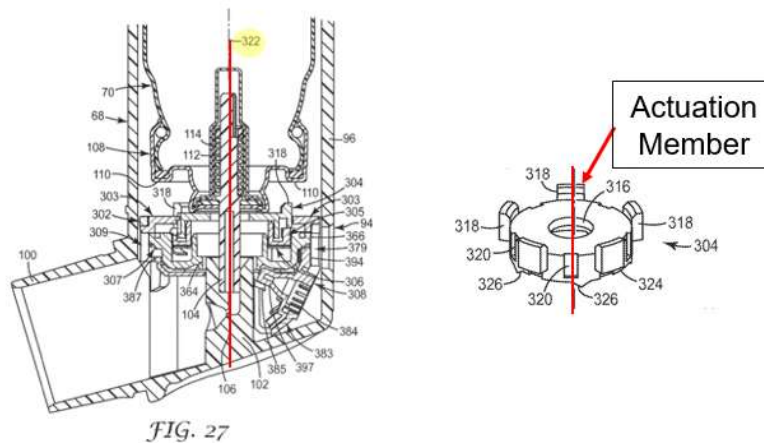


**Fig. 8a**

DTX-165 at Fig. 8a (annotated). The '514 Publication expressly states that these ribs are used for “supporting the container in the correct position,” *id.* at 14:17-19, and would have been understood to “reduce rocking.” *See* Tr., 235:12-21; 238:15-20; 238:25-239:6 (Dr. Lewis’s expert report read into record by counsel stating that ribs “necessarily” reduce rocking).

ii. ***The Addition of the '514 Publication's Four Ribs to the '406 Publication Meets the "Common Plane Limitation"***

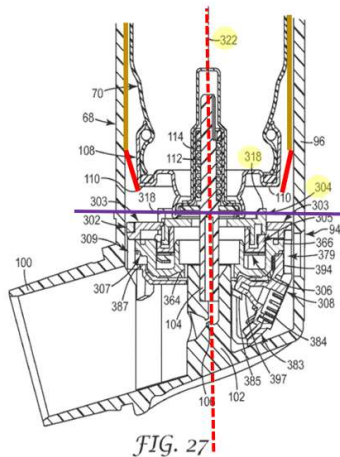
The combination of the '514 Publication with the '406 Publication discloses the Common Plane Limitation. FOF/COL, ¶¶ 157-168. The '406 Publication discloses that the canister housing has a longitudinal axis X passing through the center of the central outlet port and the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X. Mr. Anderson testified using annotated versions of Figs. 21 and 27, reproduced below, stating that he had “highlighted the axis of the actual cross-section of the '406 product [sic]. You can see that it has a longitudinal axis. So we highlighted that, 322. But we've also got the actuation member or the indexer [318] from the '406 Publication as well.” Tr., 577:1-5.



DTX-161 at Figs. 21 and 27 (annotated). Mr. Anderson provided a second annotated version of Fig. 27, reproduced below, to explain that the '406 Publication, combined with the '514 Publication, discloses the common plane limitation, explaining:

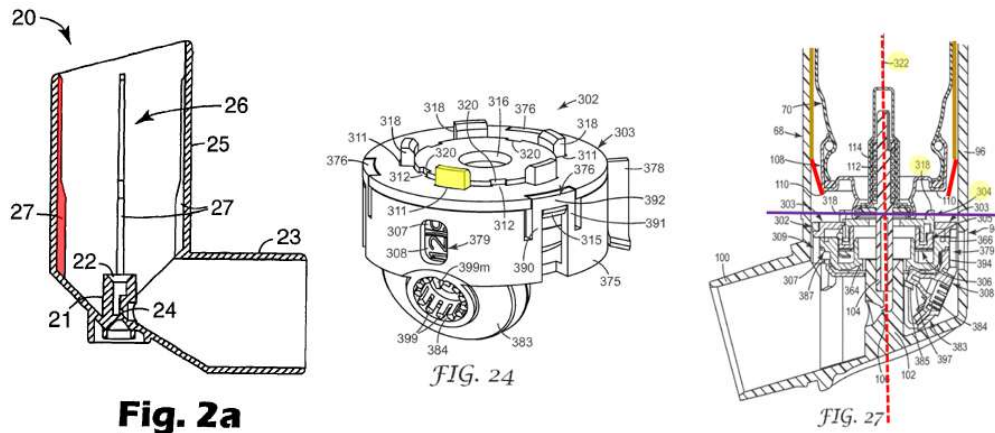
[T]he canister housing, [with] the longitudinal axis, which passes through the center of the central outlet port. We've got the inner wall support formation. We've got the actuation member. And we've got the line in an axis in a plane coincident with a longitudinal axis. And as we have been discussing, the '514 [Publication] discloses the inner wall canister support formation. That is the red. . . the common plane, which is the purple line, that purple line goes through the central outlet port. It goes through the inner wall canister support formation. . .

Tr., 577:17-578:5.



DTX-161 at Fig. 27 (annotated). Mr. Anderson's testimony is supported by the disclosures of the '406 Publication and '514 Publication. FOF/COL, ¶¶ 163-165. The '406 Publication discloses a canister housing having a longitudinal axis X (axis 322), which passes through the center of the central outlet port. *See, e.g.*, DTX-161 at Figs. 21 and 27. The '406 Publication discloses a single castellation 318 as an actuation member, the central outlet port, and longitudinal axis X, which would lie in a common plane. *See* DTX-161, Figs. 28 and 24; Tr., 577:17-578:5. The '514 Publication discloses four equally spaced inner wall canister formations. *See* DTX-165 at Fig. 8a; *see also id.* at 25:19-22 and Figs. 11a, 12a. If the four equally spaced

ribs of the '514 Publication were added to Figure 27 of the '406 Publication, one or more of them would be in the pre-existing plane that intersects with the castellation, central outlet port, and longitudinal axis X. Tr., 577:17-578:5. This is also illustrated by Fig. 2a of the '514 Publication and Figs. 24 and 27 of the '406 Publication:



DTX-165 at Fig. 2a (colored); DTX-161 at Figs. 24 and 27 (colored and annotated). The “actuation members” 311 (yellow) in Fig. 24 are aligned perfectly with the rear facing dose-counter display and the axis through the center of the outlet port. The use of four equally spaced ribs where one rib is facing towards the rear of the device as shown in Fig. 2a (red) of the '514 Publication would meet the Common Plane Limitation when combined with the '406 Publication. FOF/COL, ¶ 165.

Dr. Lewis all but admitted the combination meets this limitation. When discussing infringement, Dr. Lewis testified the fact the three features are lying in a straight line is “all I need to know” when analyzing the common plane limitation. Tr., 175:16-176:8; 209:21-210:1. Despite willingly answering numerous questions

on direct asking him to assume certain facts (Tr., 680:9- 681:11; 682:3-16; 688:9-689:5; 692:22-693:12; 694:4-695:5; 699:1-22; 712:2-14), Dr. Lewis sacrificed his credibility by refusing to confirm the combination of the '514 Publication with the '406 Publication would meet the Common Plane Limitation because “someone skilled in the art wouldn’t do that . . . .” Tr. 796:6-17. Dr. Lewis notably did not say the limitation would not be met by the combination, but rather only that in his opinion a POSA would never have added the conventional ribs to the “fantastic” design of the '406 Publication. By failing to respond to such a simple question and in view of his willingness to make assumptions in his direct testimony, Dr. Lewis’s testimony is not credible. FOF/COL, ¶¶ 207-211. The obvious addition of conventional ribs of the '514 Publication to the fantastic design of the '406 Publication is not inventive.

### **3. A POSA Would Have Been Motivated to Modify the '406 Publication and Would Have Reasonably Expected Success**

A POSA would have been motivated to combine the disclosures of the '514 and '406 Publications and would have had a reasonable expectation of success in doing so. Tr., 576:11-12; FOF/COL, ¶¶ 151-155. The '406 Publication explicitly discloses the compatibility of its dose-counter with a variety of standard inhaler housing designs. DTX-161 at [00105]. Although the figures in the '406 Publication do not include an inner wall canister support formation, the addition of such structure

would have been obvious to a POSA, given the ubiquitous use of ribs in inhaler bodies. FOF/COL, ¶¶ 59-65, 148-155.

Mr. Anderson explained how “ribs have been used . . . in the main body for many, many years. . . . And I believe 1965 was the first year that they were actually mentioned, you know, in publications, in papers. So these ribs are not new. They have been around almost as long as the MDIs themselves.” Tr., 570:6-14. In addition to the ’514 Publication, Mr. Anderson provided numerous other examples of ribs in prior art inhalers. Tr., 570:15-571:17; 571:20-572:19; DTX-137 at 5:37-40; DTX-174 at Fig. 6, DTX-165 at Fig 8a; DTX-172 at Fig. 1C; DTX-153 at Fig. 7. In view of the above disclosures, as well as the knowledge of a POSA, Mr. Anderson concluded that “ribs were ubiquitous prior art” as of 2010. Tr., 571:16-17. Mr. Anderson explained that by “2010 the use of ribs were ubiquitous and all over the industry. They were known. It doesn’t cost you anything to add a rib, so why wouldn’t you put it in to enhance the product.” Tr., 575:1-4.

A POSA would have recognized the many benefits of including ribs in an inhaler, including drawing air into the inhaler, helping put the canister into the valve stem block, and preventing accidental opening of the valve. Tr., 574:12-25, 575:8-21; FOF/COL, ¶¶ 151-152. As Mr. Anderson explained, there were “[y]ears of evidence indicating the benefits” of ribs. *Id.* at 575:22-23.

Even Plaintiffs' expert, Dr. Lewis, admitted that ribs are an "important design" in inhalers. *See* Tr., 779:15. Dr. Lewis also acknowledged that use of ribs to locate the canister was conventional long before 2009. Tr., 788:18-19. Dr. Lewis's own article cites United Kingdom Patent No. GB 994,755, which published in 1965, as teaching these ribs ("the '755 Patent") (DTX-168). Tr. 781:13-782:9; PTX-099 at 245 (Dr. Lewis' article citing the '755 patent). The '755 Patent teaches that ribs are useful to "support a pressurized container" and prevent movement of the container leading to "leakage around the valve stem[.]" DTX-168 at 1:63-67. The ribs provide "supporting engagement with the container body" and create a passageway for "scavenging air." *Id.* at 1:68-83. The '755 Patent illustrates that these four ribs are equally spaced around the inner circumference of the inhaler body and extend inwardly to support the container." *Id.* at 2:45-56 and Figs. 1-4. Accordingly, it was known well before 2009 that ribs can prevent canister movement and reduce rocking, in addition to the benefits described by Mr. Anderson. FOF/COL, ¶¶ 59-63, 152.

Even Plaintiffs' own inventors agreed that the use of ribs were commonplace in the art. FOF/COL, ¶¶ 64-65. Mr. Walsh testified that prior to the addition of a dose-counter, Teva's products already had ribs and that the inventors merely modified the "guide-rails that were already there." *Id.* at 78:3-19; 113:15-18. And despite the purported importance of adding the ribs, Mr. Walsh could not recall who actually came up with the idea. *Id.* at 112:14-23. Mr. Walsh testified that canister

rocking “exists in most of these types of inhalers,” *id.* at 80:13-25, and Mr. Karg testified he was not “aware of any inhalers that didn’t rely on support rails to prevent canister rocking.” *Id.* at 635:9-11. Given that the art taught ribs could be used to prevent canister movement, their inclusion to solve counting problems would have been obvious. FOF/COL, ¶¶ 59-65, 148-155.

In fact, it would have been unexpected to **not** include ribs in an inhaler. As Mr. Anderson explained, “[y]ears of evidence indicat[e] the benefits [of ribs]. We have been doing it for a long, long time. To actually **not** do it, you would have to challenge that.” Tr., 575:22-24 (emphasis added). A POSA “would find it difficult to find a reason not to” include ribs in an inhaler. Tr., 576:1-2.

The fact that Dr. Lewis’ believes a POSA would not use ribs, an “important” and “conventional” feature of MDI bodies with known benefits, in an inhaler body used in connection with the dose-counter of the ’406 Publication strains credulity. Dr. Lewis’s contention that ribs would have impeded airflow **contradicts** the art’s express teachings that ribs **improve** airflow through the inhaler, and is, again, not credible. Tr., 779:6-781:8.

Well before the alleged invention of the ’289 Patent, using ribs within an inhaler was a known technique that had known benefits. A POSA would have been motivated to use these ribs with the ’406 Publication. The results of adding ribs to the inhaler body of the ’406 Publication would have been no more than “a

combination of familiar elements according to known methods” that yielded predictable results. *KSR*, 550 U.S. at 401. Accordingly, claim 1 of the ’289 Patent would have been obvious over the ’406 Publication with the ’514 Publication. FOF/COL, ¶¶ 242-247.

**B. Claims 2, 4, 6, and 7 of the ’289 Patent Would Have Been Obvious over the ’406 Publication in Combination with the ’514 Publication**

Claim 2 of the ’289 Patent recites the inhaler as claimed in claim 1 “wherein the medicament canister is movable relative to the dose-counter.” Given Plaintiffs’ accusations of infringement against an identical design, there can be no good faith argument the ’406 Publication in combination with the ’514 Publication does not meet this limitation. FOF/COL, ¶¶ 175-177. Mr. Anderson confirmed this, and Dr. Lewis did not contend otherwise. Tr., 578:16-22.

Claim 4 of the ’289 Patent recites the inhaler of claim 1, “wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body.” Mr. Anderson explained that the ’406 Publication in combination with the ’514 Publication discloses this limitation. Tr., 579:8-16; DTX-165 at Fig. 8(a), Fig. 2a; FOF/COL, ¶¶ 178-180.

Claim 6 of the ’289 Patent recites the inhaler of claim 4 further “comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body.” Mr. Anderson explained that this limitation can be found in the ’514 Publication and explained why a POSA would have been motivated to

include these support rails in the '406 Publication, with a reasonable expectation of success. Tr., 580:1-8; DTX-165 at Fig. 8a, Fig. 2a; FOF/COL, ¶¶ 181-183.

Claim 7 recites the inhaler as claimed in claim 6, “wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other.” Mr. Anderson again showed that this limitation is disclosed in the '514 Publication in combination with the '406 Publication. Tr., 280:20-281:2; DTX-165 at Fig. 8a, Fig. 2a; FOF/COL, ¶¶ 184-185.

A POSA would have been motivated to add the four ribs disclosed in the '514 Publication as previously discussed, and such structure would meet the additional limitations of claims 2, 4, 6, and 7. Thus, claims 2, 4, 6, and 7 of the '289 Patent would have been obvious. FOF/COL, ¶¶ 242-247.

### **C. Plaintiffs' Other Criticisms are Unsupported and Irrelevant**

#### **1. The Four Equally Spaced Ribs Disclosed in the '514 Publication Would Necessarily Reduce Rocking**

Any contention that the four equally spaced ribs disclosed in the '514 Publication (Figs. 2a and 8a) are not “canister support formations” because they are not “a formation arranged to reduce canister rocking” is unsupported, given at least Dr. Lewis's infringement testimony. Dr. Lewis testified a rib is arranged to reduce canister rocking if the canister touches it “before [the canister] touches the inner wall.” Tr., 213:1-16. Unlike the **alleged** inner wall canister support formation in Cipla's Product (the tiny dose-counter locating rib at the front of the inhaler body

that does not reach the top of the inhaler), the ribs in the '514 Publication—like the ribs disclosed by the Asserted Patents—go to the top of the inhaler body. Accordingly, if rocked, the canister would necessarily contact the ribs before the inhaler wall, and therefore the ribs of the '514 Publication are “canister support formations,” as construed in this case. FOF/COL, ¶¶ 186-188.

In addition, Dr. Lewis’s expert report—read into the record at trial multiple times by his own counsel—confirms that Plaintiffs’ position is that by extending into the cavity of the inhaler, ribs “necessarily limit[] the canister’s freedom of movement.” Tr., 235:12-21; 238:15-20; 238:25-239:6. If Plaintiffs’ infringement position is adopted, there is no question that the ribs of the '514 Publication are canister support formations. FOF/COL, ¶¶ 186-188.

## **2. A POSA is Presumed to Have the '406 Publication’s “Fantastic” Design in Their Possession**

The POSA “is presumed to know all the pertinent prior art,” *In re Carlson*, 983 F.2d 1032, 1038 (Fed. Cir. 1992), and Cipla is not required to show a POSA would have selected the '406 Publication as the starting point over other options. *See, e.g., Novartis Pharms. Corp. v. West-Ward Pharms. Int’l*, 923 F.3d 1051, 1059-60 (Fed. Cir. 2019) (district court erred by requiring clear and convincing evidence a POSA would have selected a particular compound over other possible choices). Plaintiffs’ arguments are contrary to law. The question is whether a POSA would have been motivated to modify the '406 Publication, not whether a POSA would

have been motivated to select the '406 Publication as a starting point over all other references. *See, id.*; FOF/COL, ¶ 220.

Regardless, the record reflects a myriad of reasons why a POSA would have started with the '406 Publication, and why a POSA would have modified the '406 Publication by adding ribs. Mr. Anderson detailed how ribs were conventionally used in inhalers, Tr., 570:15- 571:17, something confirmed by Dr. Lewis's writings outside of the context of this litigation. Tr., 779:4-12. The '406 Publication also disclosed a dose-counter developed by 3M, which Dr. Lewis agreed was a "big name in inhalers" and "very impressive." Tr., 776:1-1-18. Dr. Lewis admitted the design of the '406 Publication was "fantastic." *Id.* at 748:8-14. The '406 Publication's design is a logical starting point for a POSA. FOF/COL, ¶¶ 189-191.

### **3. Whether Figures from Different References Are Capable of Being Bodily Incorporated is Irrelevant to Obviousness.**

Plaintiffs' argument regarding how a POSA could not bodily incorporate the ribs of the '514 Publication into the inhaler body of the '406 Publication is also contrary to Federal Circuit precedent. *See, e.g.*, Tr., 703-706. Obviousness does not require a physical substitution of elements. *Etter*, 756 F.2d at 859. "What matters . . . is whether a [POSA], having the teachings of the references before him, is able to produce the structure defined by the claim[s]." *Orthopedic Equip. Co. v. U.S.*, 702 F.2d 1005, 1013 (Fed. Cir. 1983); FOF/COL, ¶ 221.

The '406 Publication expressly teaches that its dose-counter can be used with a “commercially available actuator housing profiles so that it is not necessary to change the external configurations of those actuator housings to accommodate the inventive dose counter[.]” DTX-161 at [00124]. A POSA is “a person of ordinary creativity, not an automaton,” *KSR*, 550 U.S. at 421. The POSA would have been capable of incorporating well-known rib designs in combination with the dose-counter disclosed in the '406 Publication for the reasons explained above. FOF/COL, ¶¶ 192-193.

#### **4. Dr. Lewis’s “More Obvious” Argument is Irrelevant**

Dr. Lewis’s leading direct testimony regarding his opinion about how a POSA would seek to comply with FDA guidance strains credulity, and despite spanning almost an hour of trial time, it is completely irrelevant. “[T]he obviousness inquiry does not require that the prior art combination is the ‘preferred, or the most desirable configuration.’” *See, e.g., Fleming v. Cirrus Design Corp.*, 28 F.4th 1214, 1223-24 (Fed. Cir. 2022) (quoting *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004)); *see also Bayer Pharma AG v. Watson Labs., Inc.*, 874 F.3d 1316, 1329 (Fed. Cir. 2017); FOF/COL, ¶ 222.

It appears that Plaintiffs believe Dr. Lewis’s testimony is relevant to teaching away. Tr., 38:21-25; Dkt. 199 at 49-50. This evinces a misunderstanding of what “teaching away” requires. Prior art “teaches away” if it “suggests that the line of development flowing from the reference’s disclosure is unlikely to be productive of

the result sought by the applicant.” *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006). Teaching away requires “clear discouragement” of a combination and the mere fact another solution may be considered better does not mean other solutions are non-obvious. *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1355-56 (Fed. Cir. 2012). Dr. Lewis failed to provide **any** teaching away evidence. FOF/COL, ¶¶ 194-199.

Dr. Lewis contends that a POSA would not have selected a “dose counter” over a “dose indicator.” Tr., 676:5-6. This testimony relies on the false premise that a POSA would have been developing a dose-counter from scratch. The ’406 Publication already provided a “fantastic,” known “dose counter.” Dr. Lewis testified that dose-counters were “much better” than dose indicators (*id.* at 158:19-23), and he presented no evidence of why a POSA would have been discouraged from selecting a known dose-counter like the ’406 Publication. FOF/COL, ¶¶ 196-197. Indeed, Dr. Lewis’s reliance on the Stuart 2013 article is curious. Tr., 677:3-6, 740:17-741:4. Mr. Stuart is a named inventor on the ’406 Publication, which expressly states that it solves potential problems identified in Stuart 2013, including concerns regarding airflow. DTX-161, [00151]. The fact Mr. Stuart already solved these issues shows the claimed subject matter would have been obvious. *See* Tr., 740:17-745:13, 746:4-747:20; *see generally*, DTX-161; FOF/COL, ¶ 196.

Dr. Lewis's contention that a POSA would have selected a "top" of the canister dose-counter is also irrelevant. The POSA is not someone who will only engage in "the most risk-free direction." Tr., 681:5-11; *KSR*, 550 U.S. at 421 ("a person of ordinary creativity [is] not an automaton"). Yet Dr. Lewis transforms the POSA into an automaton, who would not place a dose-counter inside an inhaler because "it would cause an awful lot of effort." Tr., 683:20-684:6. But the '406 Publication already successfully accomplished this. Dr. Lewis's timidity is simply irrelevant to whether a POSA would have found the asserted claims obvious given the teachings of the prior art. FOF/COL, ¶ 198.

## **VII. THE ASSERTED CLAIMS OF THE '587 PATENT ARE INVALID**

Claims 1, 2, 4, 6, 7, and 12 of the '587 Patent would have been obvious over the '406 and '514 Publications. Tr., 564:1-4, 9-19; 564:25-565:17.

### **A. Claim 1 of the '587 Patent Would Have Been Obvious Over the '406 Publication with the '514 Publication**

Claim 1 of the '587 Patent only differs from claim 1 of the '289 Patent in that it recites the purpose of the Common Plane Limitation ("such that the first inner wall canister support formation protect against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler"). Compare JTX-003 at claim 1 with JTX-004 at claim 1. The following table shows the only "differences" in claim language:

'289 Patent Claim 1	'587 Patent Claim 1
wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.	wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, <b><u>and wherein the first</u></b> inner wall canister support formation, the actuation member, and the central outlet port <b><u>lie</u></b> in a common plane coincident with the longitudinal axis X <b><u>such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.</u></b>

The purpose language does not change the invalidity analysis outlined above in Section VI.A. Tr., 583:3-21. During prosecution of the '587 Patent, the examiner issued a double patenting rejection in view of the '289 Patent. *See* JTX-008 ('587 Patent Pros. History) at TEVAQVAR-00028862. The examiner stated that the claims of the '289 Patent and the pending claims of the '587 Patent “are not patentably distinct from each other because the ['587 Patent] claims recite the purpose for having the inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane with the longitudinal axis X, whereas the '289 patent recites just the structure without the purpose. The purpose does not have patentable weight....” *Id.* Teva did not argue otherwise, and overcame this rejection by filing a terminal disclaimer. *Id.* at TEVAQVAR00028882-28884.

The examiner was correct that adding a statement of purpose or intended use to the claimed structure does not render that structure patentable. *See, e.g., In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (“It is well settled that the recitation of a new intended use for an old product does not make that old product patentable” (collecting cases)); *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002) (the patentability of an apparatus claim “depends on the claimed structure, not on the use or purpose of that structure”). The purpose language of the ’587 Patent is nothing more than an intended use for the recited structure. It adds nothing structural, and therefore, no patentable weight. *See Schrieber*, 128 F.3d at 1477. Teva has not shown otherwise. Therefore, claim 1 of the ’587 Patent is not patentably distinct from claim 1 of the ’289 Patent, and, like the ’289 Patent, is invalid as obvious in view of the ’406 Publication with the ’514 Publication, for the reasons stated above in Section VI.A. FOF/COL, ¶¶ 124-133.

Regardless, the structures recited in claim 1 of the ’587 Patent are disclosed by the combination of the ’406 and ’514 Publications, including the Common Plane Limitation. *See supra*. As explained above, because the ribs of the ’514 Publication extend to the top of the inhaler body, they are canister support formations that will reduce rocking. *See supra*. Thus, they would satisfy the additional purpose language in claim 1 of the ’587 patent. FOF/COL, ¶¶ 169-174, 248-254.

**B. Claim 12 of the '587 Patent Would Have Been Obvious Over the '406 Publication in Combination with the '514 Publication**

Claim 12 differs from claim 1 of the '587 Patent in that the purpose differs slightly. The purpose recited in claim 12 of the '587 Patent is as follows: “such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member.” *Compare* JTX-004 at claim 1 with JTX-004 at claim 12. The following table shows the only “differences” in claim language.

'587 Patent Claim 1	'587 Patent Claim 12
unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.	<u>dose count errors</u> by reducing rocking of the medicament canister <u>towards or away from the actuation member</u> .

The amended purpose language does not change the invalidity analysis outlined above in Section VI.A. *See supra* Section VII.A (citing cases); Tr., 583:3-21 and 584:9-17. Here too, the examiner correctly found the purpose limitation added to the claims of the '587 Patent carries no patentable weight. *See* JTX-008 at TEVAQVAR-00028862. As such, claim 12 of the '587 Patent is invalid as obvious in view of the '406 Publication with the '514 Publication for the same reasons as explained above with respect to claim 1 of the '289 Patent. *See* Section VI.A. Even if the purpose limitation has patentable weight, claim 12 of the '587 Patent would have been obvious for the same reasons as explained above for claim 1 of the '587 Patent. FOF/COL, ¶¶ 169-174, 248-254.

**C. Claims 2, 4, 6, and 7 of the '587 Patent Would Have Been Obvious Over the '406 Publication in Combination with the '514 Publication**

Claims 2, 4, 6, 7, of the '587 Patent are virtually identical to claims 2, 4, 6, and 7 of the '289 Patent, respectively. The following table shows the only “differences” in claim language.

'289 Patent Claims 2, 4, 6-7	'587 Patent Claims 2, 4, 6-7
6. The inhaler as claimed in claim 4 further comprising a plurality of support rails each of which extends longitudinally along <u>an</u> inside surface of the main body.	6. The inhaler as claimed in claim 4 further comprising a plurality of support rails each of which extends longitudinally along <u>the</u> inside surface of the main body.

As explained above, claim 1 of the '289 Patent and claim 1 of the '587 Patent are indistinguishable for patentability. *See* Section VII.A. As claims 2, 4, 6, and 7 of the '289 Patent are virtually indistinguishable from claims 2, 4, 6, and 7 of the '587 Patent, claims 2, 4, 6, and 7 of the '587 Patent are invalid for the same reasons as explained above for claims 2, 4, 6, and 7 of the '289 Patent. *See* Section VII.C; FOF/COL, ¶¶ 175-185, 248-254.

## **VIII. CONCLUSION**

Plaintiffs have attempted to stretch the Asserted Claims to cover Cipla's dose-counter and inhaler body design that looks and operates nothing like the tape-based dose-counter and single actuation pin inhaler body device described and claimed in the Asserted Patents. Plaintiffs are incorrect on infringement. But if Plaintiffs were correct, there can be no question that the Asserted Claims are invalid.

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